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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,026	10/21/2005	Hideaki Shimada	Q90951	1874

23373 7590 05/11/2007

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EXAMINER	
CARLSON, KAREN C	
ART UNIT	**PAPER NUMBER**
1656	

MAIL DATE	DELIVERY MODE
05/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/554,026	SHIMADA ET AL.	
	Examiner	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *3, 4, 6, and 8-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Liu Seq Alignment*.

Applicant's election without traverse of Group 1, Claims 1, 2, 5, and 7 in the reply filed on March 26, 2007 is acknowledged.

Claims 1-14 are currently pending. The Examiner has withdrawn Claims 3, 4, 6, and 8-14 from further consideration because these claims are drawn to non-elected inventions. Claims 1, 2, 5, and 7 are currently under examination.

Benefit of priority is set to April 21, 2003.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 2, 5, and 7 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims do not recite that the product has been isolated or purified or acted on by the hand of man such that the product is taken from its naturally occurring source. Therefore, the claimed product reads on a product of nature and is non-statutory

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 5, and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 1, "apoptosis inducing agent" implies a single compound. Thus, when this agent is considered to be an active ingredient, it appears that this compound and other compounds are present as in a composition rather than a singular agent. Please clarify.

In Claim 2, it is not clear if the partial peptide is considered to also have the activity of inducing apoptosis. Additionally, an addition derivative to the SEQ ID NO: 2 may be a His tag – see Liu et al. below. Thus, a His tag could represent a partial peptide of an addition derivative of SEQ ID NO. 2. For examination purposes, it is being interpreted that this partial fragment does have said activity. Applicants may wish to amend to the claim to clearly state that the fragment has apoptosis inducing activity.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Note that Liu et al.'s FIR is cited at pages 4, line 22 of the specification, and at page 10 last paragraph through page 11 FIR is cited with other proteins known to interact with FUSE binding protein.

Claims 1, 2, 5, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Liu et al. (2000; The FBP interacting repressor targets TFIIH to inhibit activated transcription. Molecular Cell 5: 331-341).

Liu et al. teach FUSE binding protein interacting repressor (FIR) consisting of SEQ ID NO: 2 – see the amino acid sequence at Fig. 2A and the sequence alignment attached to this Office Action. Liu et al. also made derivatives of FIR. For example, Liu et al. made deletion derivatives consisting of amino acids 145-542 and 1-377 of FIR (page 339, left col., line 26) and addition derivatives of SEQ ID NO: 2 with GST or His tag (page 339, left col., line 24), or a combination of the two – GAL4 chimeras comprising amino acids 1-121, 55-542, or 121-542 of FIR (page 339, left col., lines 28-29) and GST chimeras comprising amino acids 1-113 (page 339, right col., "Helicase Assay"). Chimeras comprising N-terminally truncated FIR are also considered to be substitution derivatives of FIR.

Therefore, Liu et al. teach FIR, an agent that interacts with FUSE binding protein (**Claim 1**). FIR consists of SEQ ID NO: 2 and Liu et al. made derivates of SEQ ID NO: 2 comprising amino acid deletions, substitutions, and additions, and partial fragments thereof (**Claim 2**). At page 15, paras. 2 and 3 of the specification, the specification states that a protein can be prepared to have a form that can be introduced into cells without changing structure and function of the protein and such introduction can be made by a micro-injection method. Thus, the purified form of FIR is in a form for introduction into cells via microinjection, for example (**Claims 5**). **Claim 7** is included in this rejection because the intended use of the product does not provide a patentable limitation to the product as claimed.

The demonstration of a new activity for a known protein is considered to be further characterization of the known protein and is not evidence of novelty for the protein.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen Cochrane Carlson PhD

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KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

Attachment to office Action KCC

```
<!--StartFragment-->RESULT 1
Q9NZA0_HUMAN
ID   Q9NZA0_HUMAN   PRELIMINARY;   PRT;   542 AA.
AC   Q9NZA0; Q96H63;
DT   01-OCT-2000, integrated into UniProtKB/TrEMBL.
DT   01-MAR-2002, sequence version 2.
DT   25-JUL-2006, entry version 34.
DE   FBP-interacting repressor (Fuse-binding protein-interacting repressor,
DE   isoform b).
GN   Name=FIR; Synonyms=SIAHBP1;
OS   Homo sapiens (Human).
OC   Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
OC   Mammalia; Eutheria; Euarchontoglires; Primates; Haplorrhini;
OC   Catarrhini; Hominidae; Homo.
OX   NCBI_TaxID=9606;
RN   [1]
RP   NUCLEOTIDE SEQUENCE.
RA   Liu J., He L., Collins I., Ge H., Libutti D., Li J., Egly J.-M.,
RA   Levens D.L.;
RT   "The FBP Interacting Repressor Targets TFIIH to Inhibit Activated
RT   Transcription.";
RL   Mol. Cell 0:0-0(2000).
RN   [2]
RP   NUCLEOTIDE SEQUENCE.
RA   Liu J., Levens D.L.;
RL   Submitted (NOV-2001) to the EMBL/GenBank/DDBJ databases.
RN   [3]
RP   NUCLEOTIDE SEQUENCE.
RC   TISSUE=Muscle;
RX   MEDLINE=22388257; PubMed=12477932; DOI=10.1073/pnas.242603899;
RA   Strausberg R.L., Feingold E.A., Grouse L.H., Derge J.G.,
RA   Klausner R.D., Collins F.S., Wagner L., Shenmen C.M., Schuler G.D.,
RA   Altschul S.F., Zeeberg B., Buetow K.H., Schaefer C.F., Bhat N.K.,
RA   Hopkins R.F., Jordan H., Moore T., Max S.I., Wang J., Hsieh F.,
RA   Diatchenko L., Marusina K., Farmer A.A., Rubin G.M., Hong L.,
RA   Stapleton M., Soares M.B., Bonaldo M.F., Casavant T.L., Scheetz T.E.,
RA   Brownstein M.J., Usdin T.B., Toshiyuki S., Carninci P., Prange C.,
RA   Raha S.S., Loquellano N.A., Peters G.J., Abramson R.D., Mullahy S.J.,
RA   Bosak S.A., McEwan P.J., McKernan K.J., Malek J.A., Gunaratne P.H.,
RA   Richards S., Worley K.C., Hale S., Garcia A.M., Gay L.J., Hulyk S.W.,
RA   Villalon D.K., Muzny D.M., Sodergren E.J., Lu X., Gibbs R.A.,
RA   Fahey J., Helton E., Ketteman M., Madan A., Rodrigues S., Sanchez A.,
RA   Whiting M., Madan A., Young A.C., Shevchenko Y., Bouffard G.G.,
RA   Blakesley R.W., Touchman J.W., Green E.D., Dickson M.C.,
RA   Rodriguez A.C., Grimwood J., Schmutz J., Myers R.M.,
RA   Butterfield Y.S.N., Krzywinski M.I., Skalska U., Smailus D.E.,
RA   Schnerch A., Schein J.E., Jones S.J.M., Marra M.A.;
RT   "Generation and initial analysis of more than 15,000 full-length human
RT   and mouse cDNA sequences.";
RL   Proc. Natl. Acad. Sci. U.S.A. 99:16899-16903(2002).
RN   [4]
RP   NUCLEOTIDE SEQUENCE.
RC   TISSUE=Muscle;
RA   Strausberg R.;
RL   Submitted (MAY-2001) to the EMBL/GenBank/DDBJ databases.
CC   ---------------------------------------------------------------------
CC   Copyrighted by the UniProt Consortium, see http://www.uniprot.org/terms
CC   Distributed under the Creative Commons Attribution-NoDerivs License
CC   ---------------------------------------------------------------------
DR   EMBL; AF217197; AAF27522.2; -; mRNA.
DR   EMBL; BC008875; AAH08875.1; -; mRNA.
DR   UniGene; Hs.521924; -.
DR   HSSP; P26368; 1OOP.
DR   Ensembl; ENSG00000179950; Homo sapiens.
DR   RZPD-ProtExp; RZPDo834F1014; -.
DR   RZPD-ProtExp; V0031; -.
DR   GO; GO:0000166; F:nucleotide binding; IEA.
DR   GO; GO:0003723; F:RNA binding; IEA.
DR   InterPro; IPR012677; a_b_plait_nuc_bd.
DR   InterPro; IPR006532; PolyU_bd.
DR   InterPro; IPR000504; RNP1_RNA_bd.
DR   InterPro; IPR003954; RRM_1.
DR   Pfam; PF00076; RRM_1; 2.
DR   SMART; SM00360; RRM; 2.
DR   SMART; SM00361; RRM_1; 1.
DR   TIGRFAMs; TIGR01645; half-pint; 1.
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DR   PROSITE; PS50102; RRM; 3.
KW   RNA-binding.
SQ   SEQUENCE   542 AA;  58171 MW;  2C67EBE529A0922E CRC64;

  Query Match             100.0%;  Score 2732;  DB 2;  Length 542;
  Best Local Similarity   100.0%;  Pred. No. 1.5e-151;
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Qy        361 GVITGVTPARPPIPVTIPSVGVVNPILASPPTLGLLEPKKEKEEEELFPESERPEMLSEQ 420
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Qy        421 EHMSISGSSARHMVMQKLLRKQESTVMVLRNMVDPKDIDDDLEGEVTEECGKFGAVNRVI 480
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Db        421 EHMSISGSSARHMVMQKLLRKQESTVMVLRNMVDPKDIDDDLEGEVTEECGKFGAVNRVI 480

Qy        481 IYQEKQGEEEDAEIIVKIFVEFSIASETHKAIQALNGRWFAGRKVVAEVYDQERFDNSDL 540
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Db        541 SA 542

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